APPENDIX 3

# APPENDIX 3: JCIA/PERSISTENT PIGMENT DARKENING PROTOCOL

**Japan Cosmetic Industry Association**
**Measurement Standards for UVA Protection Efficacy**

Introduction

The damaging effects of UV rays on the skin have become widely recognized by consumers, and there have been reports in the media warning of increases in the level of UV rays due to environmental pollution. This has resulted in the appearance of many "Cosmetics with UV Protection" on the market. These products protect the skin by reducing or blocking the effects of UV rays.

Cosmetics with UV Protection can be roughly divided into two groups. One is "Suntan Cosmetics" which are used for the purpose of obtaining a beautifully suntanned complexion while limiting the affects of UV rays on the skin to a minimum, the other is "Sunscreen Cosmetics" which are used for the purpose of preventing Sunburn and Suntan.

UV rays that reach the surface of the earth can be divided into the A region of UV light (UVA: 320-400 nm) and the B region of UV light (UVB: 280-320 nm), and these two types of UV rays have different effects on the skin. UVB causes erythema of the skin several hours after exposure, and several days after exposure to UVB may lead to increased pigmentation, dryness and scale. UVA causes darkening of the skin immediately after exposure (immediate pigment darkening) and in the event of exposure to large amounts of UVA, this darkening appears to be transformed to delayed pigment darkening. There are also reports that UVA increases sensitivity of the skin to UVB. In addition to these acute responses, UV rays contribute to skin cancer and to aging of the skin typified by blotches and wrinkles. The relative contributions of UVB and UVA to these various reactions are not known, but the effects of the deep penetration of UVA rays cannot be ignored.

Under these circumstances, the expression "UV Protection" (in product claims) is not always adequate, so there is a need to clarify whether a product protects against UVA or UVB, and to what extent it protects against each.

SPF is an index of the protection against sunburn provided by cosmetics with UV protection. The SPF value is determined in accordance with the Japan Cosmetic Industry Association SPF Measurement Standards (Effective from January 1992) in Japan, in accordance with COLIPA regulations (October 1994) in Europe, and in accordance with FDA regulations (Tentative Final Monograph, May 1993) in the U.S. Because these methods are quite similar, their SPF values are roughly comparable even though a uniform method is not employed worldwide. Throughout the world the SOF value acts as an index that consumers use in product selection.

With respect to an index or measurement methods for UVA protection, however, a uniform measurement method has not yet been established on a national or industry-wide level although several papers on the subject have been published, and studies are underway in various countries. Throughout the world there are products displaying numerical values, etc., for UVA protection, but because there is particular concern that a uniform measurement method has not been established in Japan and these numerical values may cause confusion among consumers in their product selection, it has been decided not to employ some types of index to list the level of UVA protection on cosmetic products.

herefore, for the purpose of establishing a method for measuring UVA protection, the Technical Committee of the Japan Cosmetic Industry Association reorganized its previous SPF task force in November 1992 and established the Ultra Violet task force. This task force has handled the basic research project on UV protection approved and

sponsored by the Japan Human Science Foundation and has compiled its results in this document.

The fundamental principles toward the standard are described below:

(1) The standard is intended to provide uniform measurement method of PFA (Protection Factor of UVA) values and labeling method for the grade of UVA protection on sunscreen and suntan cosmetics enable consumers to select products which meet consumers desired UV light protection efficacy.

(2) The standard shall go into effect on January 1, 1996.

(3) The standard shall be reviewed when new technological findings warrant it.

The standard consist of "I. Measurement Method of UVA Protection efficacy," listing itemized measurement conditions and "II. Annotation" providing practical points carry out tests using this method.

## I. PFA Measurement Method

1. Selection of Test Subjects and Test Sites (Annotation 1)

(1) Subjects must be healthy males and females at least 18 years old and belong to Skin Type II, III or IV mentioned below.

Subjects must be asked of their physical conditions and must be excluded if they have photodermatitis or take medicine (such as anti-inflammative agent, anti-hypertensive agent etc.) relating to skin's photosensitivity.

Skin Type: I. Always burns easily; never tans
II. Always burns easily; tans minimally
III. Burns moderately; tans gradually
IV. Burns minimally; always tans well
V. Rarely burns; tans profusely
VI. Never burns; deeply pigmented

The skin types are classified based on the typical skin reactions to 30 to 45 minutes sun bathing after a winter season of no sun exposure.

(2) Test site is the back, and the skin must have almost uniform color without pigmentation, nevus and so forth.

2. Number of Subjects (Annotation 2)

Each test must be performed with at least 10 subjects and the standard error for measuring PFA shall not exceed 10% of obtained PFA value.

3. Standard Sample (Annotation 3)

The standard sample shall be prepared according to the formula described below. Measurement of the standard sample shall be performed concurrently with the measurement of the test sample. Formula and Preparation method of the Standard sample (a cream containing 5% 4-tert-Butyl-4"-methoxydibenzoylmethane and 3% 2-Ethylhexyl p-methoxycinnamate).

| | | % by Weight |
|---|---|---|
| A1 | Purified Water (JSCI) | 57.13 |
| A2 | Dipropylene Glycol (JSCI) | 5.00 |
| A3 | Potassium Hydroxide (JSCI) | 0.12 |
| A4 | Trisodium Edetate (JSCI) | 0.05 |
| A5 | Phenoxyethanol (JSCI) | 0.3 |
| B1 | Stearic Acid (JSCI) | 3.0 |
| B2 | Glyceryl Monostearate, Self-emulsifying (JSCI) | 3.0 |
| B3 | Catostearyl Alcohol (JSCI) | 5.0 |
| B4 | Petrolatum (JSCI) | 3.0 |
| B5 | Glyceryl Tri-Z-ethylhexanoate (JCIC) | 15.0 |
| B6 | 2-Ethylhexyl p-Methoxycinnamate (JSCI) | 3.0 |
| B7 | 4-tert-Butyl-4'-Methoxydibenzoylmethane (JSCI) | 5.0 |
| B8 | Ethyl Parahydroxybenzoate (JSCI) | 0.2 |
| B9 | Methyl Parahydroxybenzoate (JSCI) | 0.2 |

Weigh out each of the ingredients in A, dissolve them in the purified water, and heat the solution to 70° C.
Weigh out each of the ingredients in B and heat them to 70°C so that they dissolve completely.
Add B to A, emulsify the mixture, and adjust the size of the emulsified particles with a homogenizer, etc.
Cool the emulsion to obtain the standard sample.

4. Amount of the Samples to be Applied (Annotation 4)

The amount of the samples to be applied shall be 2 mg/cm$^2$ or 2 ul/cm$^2$ each.

5. Area of the Samples to be Applied (Annotation 5)

The area (for applying samples) shall be at least 20 cm$^2$.

6. Time from Application to Exposure

Radiation exposure shall begin at lest 15 minutes after the samples are applied.

7. Light Source (Annotation 6)

An artificial light shall be used as a source of light, which must satisfy following conditions..

(1) The UV light emission is UVA range shall have a continuous spectrum similar to sun light. Moreover, the ratio of UVA I (340-400 nm) and UVA II (320-340 nm) shall be close to that of sunlight (UVA II/UVA-8-20%).

(2) To avoid extreme sunburn, UV ray shorter than 320 nm shall be excluded through the use of an appropriate filter. Monitoring and maintenance shall be performed to insure that the above conditions are always maintained.

8. Radiation Field (Annotation 7)

A single radiation field shall be at least 0.5 $cm^2$. The radiation fields of the untreated area shall be equivalent to the radiation field of the treated area.

9. Progression of UV Dose (Annotation 8)

A UV dose progresses geometrically and the increment shall be 25% maximum.

10. MPPD (Minimal Persistent Pigment Darkening Dose) (Annotation 9)

The MPPD is defined as the minimum dose of UV rays that produces slight darkening over essentially the whole radiation field within 2 to 4 hours after exposure. Determination of MPPD shall be conducted in a room with sufficient lighting at a fixed time within 2 to 4 hours after the end of exposure. At least two trained evaluators are desired to read MPPD.

11. Calculation Method of the PFA Value (Annotation 10)

PFA value shall be obtained from the following equation by using MPPDs at sites untreated and treated by a test sample.

PFA value = MPPD in protected skin/MPPD in unprotected skin

PFA value of a test sample is defined as the arithmetic mean of each subject's PFA values obtained from the above equation.

12. Method for Expressing UVA Protection (Annotation 11)

For labeling PFA values in UV protecting products, the figures to the right of the decimal point shall be discarded from the PFA value of the sample that has been calculated according to the above method to make it an integer. Then, when the value is not less than 2, it shall be classified according to the following PA (Protection grade of UVA), and this classification shall be expressed on the label. PA shall be placed together with the SPF value.

| PFA Value | PA (Protection grade of UVA) |
|---|---|
| 2 or more but less than 4 | PA+ |
| 4 or more but less than 8 | PA++ |
| 8 or more | PA+++ |

**II. Annotations**

(Annotation 1) Selection of Subjects and Test Sites

For the PFA value measurement to be an index of the persistent pigment darkening induced by UVA, it must be assumed that a stable darkening occurs from exposure to UV rays. If the skin color is dark, the determination of this reaction is very difficult. Moreover, as shown in Figure 1, no significant differences were found between PFA values obtained from skin types II, III, and IV. Therefore, skin types II, III, and IV have been stipulated. Results of a skin type survey of Japanese people conducted by the Japan Cosmetic Industry Association show that approximately 74% of Japanese belong to skin types, II, III and IV>

The subjects shall be selected from applicants who understand the objective of the test by interview questions in the "Questionnaire for subject Selection". Examples of drugs that contribute to photosensitivity include the following:

- Hypotensive agents, psychotropic agents, tranquilizers, antihistamines, oral hypoglycemic agents, and tetracycline antibiotics.

Because it is necessary for the test subjects to evaluate their own skin types and agree to being a test subject, the minimum age for test subjects was set at 10 and above. It is also recommended that subjects not be older than 60 years old.